

-5-

REMARKS

Claims 1-3, 5-20, 31 and 32 are pending in the application. Claims 1 and 10 have been amended. No new matter has been added. Reconsideration of the claims is respectfully requested.

Claims 1-2, 6-7, 10, 13-14, and 16-19 are rejected under 35 U.S.C. §102 (b) as being anticipated by Scott et al. (US 5,383,928). Applicants respectfully traverse the rejection.

Scott et al. relate to a stent encompassed by a polymer sheath which will locally deliver a drug to an arterial wall or lumen into which the stent has been inserted (col. 5, lines 27-28, col. 6, lines 38-39). As shown in Figure 3, the stent is only encompassed on its outer surfaces by the sheath. There are clearly two separate parts in Scott, the stent and the polymer sleeve or sheath (col. 10, line 4). Scott also describes a kit comprising a sheath and a stent, and that the stent is inserted into the sheath (col. 5, lines 26-29, col. 6, lines 37-38). Thus, the polymer sheath covers only the outer surfaces of the stent, and does not cover all of the substrate as in Applicants' claims 1 and 10. Further, the polymer sheath does not form a structure shaped differently from the structure of the substrate.

In Applicants' claims, the polymer covers all of the substrate. The polymer provides a biocompatible material for use in medical devices that contact bodily fluids. Page 6, lines 8-16. In addition, the polymer forms a structure shaped differently from the structure of the substrate. Scott does not teach every element of claims 1 and 10, and therefore fails to anticipate claims 1 and 10.

It is believed that the rejections of dependent claims 2, 6-7, 13-14, and 16-19 are moot in view of the amendments and remarks made in connection with independent claims 1 and 10. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features with further distinguish these claims from the cited reference.

- 6 -

Applicants respectfully request withdrawal of the rejection of claims 1-2, 6-7, 10, 13-14, and 16-19 under 35 U.S.C. §102(b) as being anticipated by Scott et al.

Claims 3, 8, 9 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Scott in view of Reimink et al. (US 5,910,170). Claims 5 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Scott in view of Gaterud et al. (US 5,522,882). Claims 5, 12 and 31-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Scott in view of Ashiya et al. (US 5,947,925). Applicants respectfully traverse the rejections.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicant respectfully traverses the rejection since the prior art fails to disclose all the claim limitations.

As discussed above, the polymer sheath in Scott does not cover all of the substrate as in Applicants' claims 1 and 10. Further, the polymer sheath in Scott does not form structures shaped differently from the structure of the substrate. Reimink, Gaterud, and Ashiya do not supply these deficiencies.

It is believed that the rejections of dependent claims 3, 5, 8, 9, 12, 15, 31 and 32 are moot in view of the amendments and remarks made in connection with independent claims 1 and 10. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features with further distinguish these claims from the cited reference.

Applicants respectfully request withdrawal of the rejection of claims 3, 8, 9 and 15 under 35 U.S.C. §103(a) as being unpatentable over Reimink et al. Applicants respectfully request withdrawal of the rejection of claims 5 and 32 under 35 U.S.C. §103(a) as being unpatentable over Gaterud et al. Applicants respectfully

- 7 -

request withdrawal of the rejection of claims 5, 12 and 31-32 under 35 U.S.C. §103(a) as being unpatentable over Ashiya et al.

Claims 10-11 and 15-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenkei (US 4,597,767) in view of Reul et al. (US 4,263,680). Claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lenkei in view of Reul and further in view of Sumitomo Electric Co. (Abstract, JP 59192366). Applicants respectfully traverse the rejections since the prior art fails to disclose all the claim limitations, as amended, and there would be no motivation to combine the references as proposed by the Examiner.

Lenkei relates to a medical device which comprises a heart valve prosthesis having leaflets of a metal foil or pyrolytic carbon. Col. 4, lines 19-21. Reul et al sets forth a valve member that comprises a metal coated with a first layer of a polymer (epoxy). The metal with polymer layer is then covered with a second layer of material such that the polymer is between the metal and the material. Col. 4, lines 30-33. Thus, since the polymer (epoxy) layer is covered by a second layer, the polymer layer does not contact bodily fluids, and does not separate the bodily fluids from the substrate, as set forth in Applicants' claim 10. Sumitomo Electric does not supply the deficiencies in the combination of Lenkei and Reul. Thus, a *prima facie* showing of obviousness has not been shown as to claim 10 by the combination of Lenkei and Reul, or the combination of Lenkei, Reul and Sumitomo.

It is believed that the rejections of dependent claims 11 and 15-19 are moot in view of the remarks made in connection with independent claim 10. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features with further distinguish these claims from the cited reference.

Applicants respectfully request withdrawal of the rejection of claims 10-11 and 15-19 under 35 U.S.C. §103(a) as being unpatentable over Lenkei in view of Reul et al. Applicants respectfully request withdrawal of the rejection of claim 20 under 35 U.S.C. §103(a) as being unpatentable over Lenkei in view of Reul et al, and further in

- 8 -

view of Sumitomo Electric Co.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicant respectfully requests favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Hallie A. Finucane at 612-334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

WESTMAN, CHAMPLIN & KELLY, P.A.

By: Hallie A. Finucane
Hallie A. Finucane, Reg. No. 33,172
Suite 1400 - International Centre
900 Second Avenue South
Minneapolis, Minnesota 55402-3319
Phone: (612) 334-3222 Fax: (612) 334-3312

HAF:lms